

Appendix V

Sample Consent for Infant Participation

REMINDER TO STUDY SITES: Do not use the preamble in local consents.

NOTE FROM THE OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP) TO SITES ENROLLING PARTICIPANTS IN THIS STUDY:

Please note that this sample language does not preempt or replace local Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) review and approval. Investigators are required to provide the local IRB/IEC with a copy of this sample language along with the language intended for local use. Local IRBs/IECs are required to weigh the unique risks, constraints and population considerations as a condition of any approval. Any deletion or substantive change of information concerning risks or alternative treatment must be justified by the investigator, approved by the local IRB/IEC and noted in the IRB/IEC minutes. Justification and IRB/IEC approval of such changes must be forwarded to Westat, or as may be otherwise specified. Sponsor-approved changes in a protocol must be approved by the local IRB/IEC before use unless intended for the elimination of apparent immediate hazard. New information shall be shared with existing participants at the next encounter, with all new participants prior to involvement or as the local IRB/IEC may otherwise additionally require.

TITLE OF STUDY: **Prospective Cohort Study of HIV and Zika in Infants and Pregnancy (HIV ZIP)**

Principal Investigator (PI): _____

Telephone Number: _____

Introduction

This research study is sponsored by The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) in the United States. This study is being done to see how Zika affects pregnant women with and without the Human Immunodeficiency Virus (HIV) and their babies. It is being done in Brazil, mainland United States and Puerto Rico. You are being asked to allow your baby to participate in this study because you are taking part in this study.

This consent form will help you learn about this study. You can ask the study staff any questions you have about this study at any time. If you choose to allow your baby to be in this study, you will be asked to sign this form. You will get a copy once signed.

It is important that you know:

- You choose/decide to allow your baby to be in this study or not.
- Your baby will be in this study once you deliver. This consent form is for your baby.
- If your baby joins this study, you can have your baby stop **at any time**. It will not affect any benefits your baby has, health care at the clinic or your baby's ability to be in other studies.
- At any time, you can decide that we should not collect some or all of the study samples from your baby. If this happens, your baby may or may not still be in this study. Your baby's samples are needed to test him/her for Zika.

What is Zika?

Zika is a virus that can be passed from an infected mosquito bite. It can also be spread from a mother to her unborn child while she is pregnant and during delivery.

Zika may cause severe problems for a baby, such as microcephaly. Microcephaly causes the baby's head to be very small, and keeps the brain from growing as it should. There may be other serious problems with the baby's sight, hearing or growth. Some babies may not survive at or after birth.

Why is this Study Being Done?

This study wants to see if babies born to women who have HIV or Zika, or both HIV and Zika have different or worse problems than babies born to women who do not have either HIV or Zika.

We do not know how many babies with Zika will have health problems, and what problems will occur. We do not know if Zika infection could make these problems worse. It is important to learn more about these things so that we can provide the best care and treatment for mothers and their babies with and without Zika and with and without HIV.

What Does My Baby Have to Do If He/She is in this Study?

If your baby is in this study, he/she will have the following visits:

- Birth visit (within 48 hours after birth, before your baby leaves the hospital)
- 3-Month visit (10-14 weeks old)
- 6-Month visit (22-26 weeks old)
- 12-Month visit (50-54 weeks old)

Each visit will last about 1 hour and a half (1 ½ hours).

The following activities will be done at all the visits:

- We will record information from your baby's medical chart on any exams and tests he/she has.
- Your baby will have a physical exam that includes measuring his/her height, weight, temperature and head circumference.
- Your baby will have tests to understand how his/her spinal cord and brain are working. During these tests, we will watch your baby's reaction to stimuli (things that cause him/her to react), test your baby's reflexes and see which position your baby prefers.
- If you had Zika during your pregnancy, your baby will have a head ultrasound at the 3-Month visit if one was not already done through his/her regular care. A head ultrasound uses sound waves to check for anything abnormal in the brain.
- Your baby may have a spinal tap as part of his/her regular care. A spinal tap is when a needle is placed in the lower part of the spine to collect and look at fluid surrounding the spinal cord and brain. If your baby has a spinal tap, we will collect some of the fluid if any is left after the doctor takes his/her samples. The spinal fluid will be stored for possible future Zika research.
- Your baby will have an eye examination. The eye specialist will look at all parts of the eyes and check for anything that is abnormal. If the exam is abnormal, the eye specialist will do more tests.
- Your baby will have a hearing test. The hearing specialist will use special equipment that will be put in or close to your baby's ear to record how well he/she can hear sound. If the test is abnormal, the hearing specialist will do more tests.
- We will collect a small amount of urine for Zika testing. We will place a plastic collection bag in your baby's genital area and leave it there until urine is passed.
- If you allow, we will store any extra urine that we collect for possible future Zika research.
- We will collect about 4 ml of blood (a little less than 1 teaspoon) from your baby. At the Birth visit, we may collect up to 7 ml of blood (a little less than 1.5 teaspoons) if your baby needs to be tested for other infections not done as part of your baby's regular care. You will be given the results of all your baby's tests.
- Any abnormal findings will be explained to you. We will guide you about what can be done to treat or provide care for any abnormal findings, whenever possible.

3-Month, 6-Month and 12-Month Visits ONLY

- You will be asked questions about your baby's health, growth and possible exposure to Zika.
- You will be asked questions about what your baby is able to do, and how you think your baby is growing.
- Your baby will have an exam that includes looking at your baby's movements, muscles and attention. This is done to see if your baby is developing as he/she should. If your baby appears to have any problems, you will be told about how we may be able to help your baby.

How Many Babies Will Be in this Study?

This study will be done in two parts. The first part will enroll all babies born to the 200 women enrolled in this first part of the study. If 200 women and their babies are enrolled in the first part, the second part will enroll all the babies born to the 1,800 women enrolled in the second part of this study.

How Long Will My Baby Be in this Study?

Your baby will be in this study from birth until he/she is about 12 months old.

What Are the Risks of this Study to My Baby?

Risks While Collecting Blood

Your baby may feel faint or feel some pain while having blood taken. There may be some tenderness, swelling, bleeding, bruising or a small risk of infection at the point where the needle goes into his/her skin. A small, brief blood clot may develop. To reduce these risks, trained staff will take your baby's blood.

Risks While Collecting Urine

There are no major risks to your baby while collecting urine. Rarely, a mild skin rash from the adhesive on the collection bag may develop.

Risks While Examining Your Baby's Ears

While examining your baby's ears, sensors will be placed near the ears. These sensors will connect with wires to a measuring device. Your baby will be given sounds to hear. The device will record your baby's brain waves while he/she listens to the sounds. Your baby may feel some discomfort while the sensors are being put in place, but the exam itself is painless.

What Are the Benefits of Taking Part in this Study?

There may be no direct benefits for your baby from being in this study. You will get the results of all Zika tests as well as other tests done for this study. Your baby's participation in this study may also help doctors learn more about health problems that Zika can cause in babies born to mothers with and without HIV. It may also help to find out ways to stop Zika from infecting babies if their mothers have Zika while pregnant. The information learned from this study may also help doctors provide better care for babies with HIV and Zika in the future.

Your baby may benefit from the close follow-up and testing to find out if he/she has any hearing, seeing or development problems. Some of these tests are not routinely performed in newborn

clinics. In addition, we can discuss treatment choices with you, such as early stimulation or hearing aids, when needed.

How Will My Baby's Privacy and Confidentiality Be Protected?

The doctors and research staff will work to keep your baby's information confidential [BRAZIL: INSERT THE FOLLOWING AT THE END OF THE SENTENCE: according to Brazilian and International rules]. Study staff sign a form promising to protect your baby's information. Your baby's name will be replaced by a special code called a Participant Identification (PID) number. The code will be used on your baby's study samples and all your baby's study forms to protect your baby's identity. The link between your baby's code and your baby's name will be kept in a locked place at the research site, separate from your baby's medical chart. Paper files will also be kept in a locked place at the research site. Computer files will be password protected. Access to all study information will be limited to people working on this study. Nothing written or published about this study will use your baby's name.

[NOT APPLICABLE FOR BRAZIL SITES: To help further protect your baby's information, a Certificate of Confidentiality will be obtained from the U.S. Department of Health and Human Services. This document protects the study staff from having to share your baby's information when asked during Federal, State, or local civil, criminal, administrative, legislative or other proceedings.

A Certificate of Confidentiality does not prevent you from giving your permission to share your baby's information if you choose. If someone (like an insurer or employer) requests your baby's laboratory results or other research information and you say it is okay, the study staff cannot use the Certificate of Confidentiality to prevent you from sharing it. This means that you must be careful about whom you choose to allow to look at your baby's research information.]

Groups in the United States such as the National Institutes of Health (NIH), Office for Human Research Protections (OHRP), study monitors and the [INSERT IRB/IEC NAME] may look at your baby's information. They make sure your baby's rights and safety are protected.

[BRAZIL: INSERT THE FOLLOWING: When agreed on by the study doctor and staff, and complying with the Code of Ethics of the Federal Counsel of Medicine and Brazilian laws that protect study participants, your baby's information may be looked at by the Ethics Committee of the Ministry of Health, and other agencies in your country that also make sure your baby's rights and safety are protected.]

Every effort will be made to keep your baby's participation and the personal information in his/her research record confidential, but absolute confidentiality cannot be guaranteed. This includes reporting infectious diseases to health authorities as required by local law. Another example is if we learn something that would immediately put your baby or others in danger, the study staff are required by law to take steps to keep your baby and others safe. This means that we have to report to the authorities (hospital, police or social services) any information you tell

us that suggests that your baby might be in danger, such as if you tell us that you or someone else have or might hurt or neglect your baby.

[PEDIATRIC HIV/AIDS COHORT STUDY (PHACS) SURVEILLANCE MONITORING FOR ART TOXICITIES (SMARTT) SITES ONLY (FOR HIV-INFECTED WOMEN ONLY)
INSERT THE FOLLOWING: If you also decide that you and your baby will participate in the Pediatric HIV/AIDS Cohort Study Surveillance Monitoring for Antiretroviral Therapy Toxicities (PHACS SMARTT) study, your baby's information from HIV ZIP (this study) will be shared with PHACS SMARTT. All information, once shared, will be protected just as it is for HIV ZIP.]

A description of this study will be available on the website: <http://clinicaltrials.gov>. The description will include a summary of the results. There will be no information that could identify your baby. You can search this website at any time.

What Are the Costs to My Baby?

There are no costs to you to have your baby take part in this study. You will not pay for your baby's study visits, physical exams or tests done for this study. Your baby's insurance company will still pay for his/her medical care that is not part of this study.

Will My Baby Receive Any Payment?

You [will/will not] be paid for your baby's time during the study visits. You [will/will not] receive money for the cost of food and transportation to bring your baby to the study visits. [INSERT ANY SITE-SPECIFIC COMPENSATION DETAILS]. Some research may lead to new things, such as new medicines or tests. Neither you nor your baby will receive any money from these new medicines or tests.

Are There Options to Being in this Study?

You may choose not to have your baby join this study. If you wish, we can tell you if we know of other studies that your baby can join.

What Happens If My Baby is Injured?

We do not think that your baby will be injured because of this study. If your baby is injured, your baby will be treated for his/her injuries related to this study for as long as needed at no cost to you [BRAZIL: INSERT AS APPLICABLE: as well as paid for possible indemnities]. [U.S.: INSERT AS APPLICABLE: The cost for this treatment will be charged to you or your baby's insurance company.]

The doctor in charge of this study at our site, [INSERT PI NAME], is responsible for making sure your baby gets this care. Your baby will not receive any money through NICHD (the study Sponsor). You will not be giving up any of your baby's legal rights by signing this consent form.

What Are My Baby's Rights as a Research Participant?

The choice for your baby to be in this study is yours, meaning it is voluntary. You will be told about new information from this or other studies that may affect your decision to have your baby stay in this study. Your decision will not affect whether or not your baby can be in other studies. It will not take away any of your baby's benefits. Tell the study staff if you want to know about the results of this study.

Can My Baby Be Taken Off this Study Early?

The study doctor may take your baby off this study early without your permission for the following reasons:

- The doctor thinks your baby could be harmed from being in this study. The doctor will inform the [INSERT IRB/IEC NAME] IRB/IEC of his/her decision. The [INSERT IRB/IEC NAME] IRB/IEC is in charge of protecting the safety and rights of the research participants at this site.
- This study is stopped by NICHD, OHRP, this site's IRB/IEC, or other governmental agencies [BRAZIL: INSERT THE FOLLOWING: or the Brazilian National IRB CONEP].
- You are not able to bring your baby to the study visits or complete the study evaluations.

If your baby is taken off this study, no more information will be collected for your baby and no more study visits will be done. The information that we have already collected about your baby will stay in this study.

What If I Have Problems or Questions?

If you have problems with or questions about this study, or in case of harm to your baby due to this study, contact [INSERT NAME AND PHONE NUMBER OF PI] or [INSERT NAME AND PHONE NUMBER OF IRB/IEC CONTACT]. The local IRB or IEC is located in [INSERT INSTITUTION NAME, ADDRESS AND PHONE NUMBER], and the hours of operation are [INSERT HOURS OF OPERATION].

Storage of Samples

Researchers in this study would also like to store your baby's samples for possible future research. Some of the research may be done to find better tests for Zika. Some of the research may be done to better understand how Zika may cause disease and problems, and how to best treat or prevent Zika and the problems it can cause.

If any of your baby's blood and urine are left after the tests have been done for this study, they will be stored for future research with your permission. In addition, we will store extra spinal fluid that is not needed by the doctor if your baby has a spinal tap as part of his/her regular care. Your baby's samples will all be kept in a special laboratory called a Biorepository. The Biorepository for this study is located in the United States (Fisher BioServices).

[NOT APPLICABLE FOR BRAZIL: Researchers may want to look at how people's genetic makeup (their DNA) either protects them or puts them at greater risk for Zika. Information from DNA testing will be very important as scientists work to better protect and treat people with Zika.]

Your baby's samples will be labeled with your baby's study code only. The document that is locked at the research site that links this code to your baby's name will not be available to anyone at the Biorepository or researchers who may use your baby's samples. Only a small group of researchers and people who work at the Biorepository will have access to your baby's stored samples. They will not be sold or used to make products that can be sold for money.

If researchers want to use your baby's stored samples, they will need permission from NICHD. [BRAZIL: INSERT THE FOLLOWING: They will also need permission from the site's IRB/IEC. According to the Brazilian rules, your baby's samples will be kept stored for up to five years. If the researchers want to keep your baby's samples for a longer time, they must provide a report to their local IRB/IEC that tells about what they plan to do with the samples.]

[NOT APPLICABLE FOR BRAZIL: You will not receive the results of research done on your baby's samples from the Biorepository. This is because samples can stay in the Biorepository for many years. There is no time limit to when studies could be done in the future. The results of these future studies will not affect your baby's care right now, but they may help other babies like yours in the future.]

You may decide that you do not want your baby's samples to be stored for future research studies. Your baby can still participate in this study even if you make this decision.

Please indicate your response to the following statement and initial in the appropriate space provided.

I agree to allow my baby's blood and urine samples to be stored for use in future NICHD [BRAZIL: INSERT THE FOLLOWING: and CEP/CONEP system] -approved related research studies.

Check one:

☐ Yes ☐ No _____ Initials ____/____/____ Date

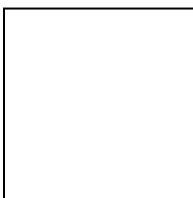
If Study Participant's Parent/Legal Guardian is Illiterate

Name of Witness

Signature of Witness

Date

Thumbprint of Participant's
Parent/Legal Guardian



[BRAZIL: INSERT THE FOLLOWING: **Please indicate your response to the following statement and initial in the appropriate space provided.**

I wish to be informed about every new future research study approved by the NICHD research network and the CEP/CONEP for researcher use of my baby's blood samples through a new Informed Consent.

Check one:

☐ Yes ☐ No _____ Initials ____/____/____ Date

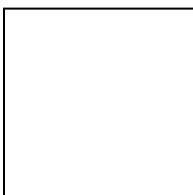
If Study Participant's Parent/Legal Guardian is Illiterate

Name of Witness

Signature of Witness

Date

Thumbprint of Participant's
Parent/Legal Guardian]



[NOT APPLICABLE IN BRAZIL: **Please indicate your response to the following statement and initial in the appropriate space provided.**

I consent (agree) to allow my baby's samples to be stored for use in future studies that will use my baby's DNA and are approved by NICHD.]

Check one:

☐ **Yes** ☐ **No** _____ Initials ____/____/____ Date

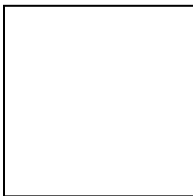
If Study Participant's Parent/Legal Guardian is Illiterate

Name of Witness

Signature of Witness

Date

Thumbprint of Participant's
Parent/Legal Guardian]



A copy of this Informed Consent Form has been provided to the participant's parent(s) or legal guardian(s): _____ (initialed by Study Personnel).

AUTHORIZATION FOR ACCESSING INFORMATION FROM YOUR BABY'S MEDICAL CHART

During your baby's participation in this study, the responsible researcher will need access to information in your baby's medical charts. **Please indicate your response to the following statement and initial in the appropriate spaces provided.**

I authorize the study investigator to access information in my baby's medical charts.

Check one:

☐ **Yes** ☐ **No** _____ Initials ____/____/____ Date

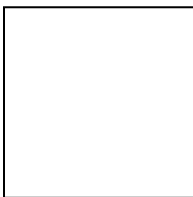
If Study Participant's Parent/Legal Guardian is Illiterate

Name of Witness

Signature of Witness

Date

Thumbprint of Participant's
Parent/Legal Guardian



Name of Study Personnel

Signature of Study Personnel

Date

Statement of Consent

The purpose of this research study, what your baby will have to do and the risks and benefits of this study have been explained to you. Any questions you have about this study have been answered. You have been told that consenting to have your baby participate in this study is voluntary. It is your choice to allow your baby to take part in this study. You may refuse to allow your baby to take part or may have your baby stop taking part at any time without it affecting your baby's future treatment at this hospital/clinic, or your relations or your baby's future relations with the hospital/clinic or its employees.

(NOTE: This is only a suggested signature format. Sites may use their own signature page.)

By signing this consent document, you are agreeing to have your baby take part in this study. You will be given a copy of this signed consent form to keep.

| | | |
|--|----------------------------------|------|
| Participant's Mother or Guardian Name (print) | Mother's or Guardian's Signature | Date |
|--|----------------------------------|------|

| | | |
|--|---|------|
| Participant's Father Name (print) (If father's consent is required) | Father's Signature (If father's consent is required) | Date |
|--|---|------|

PI or Designee's Statement:

I have reviewed this study and the consent form with the participant's parent (or legal guardian). To the best of my knowledge, the participant's parent (or legal guardian) understands the purpose, procedures, risks and benefits of this study.

| | | |
|-------------------------------|----------------------------|------|
| PI or Designee's Name (print) | PI or Designee's Signature | Date |
|-------------------------------|----------------------------|------|

| | | |
|------------------------|---------------------|------|
| Witness's Name (print) | Witness's Signature | Date |
|------------------------|---------------------|------|

NOTE: This consent form with the original signatures MUST be retained on file by the PI. A copy must be given to the participant's parent (or legal guardian). A copy should be placed in the participant's medical record, if applicable.

If Study Participant's Parent/Legal Guardian is Illiterate

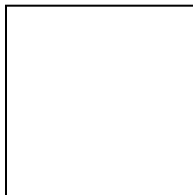
I have witnessed the accurate reading of the consent form to the potential participant's parent/legal guardian, and the individual has had the opportunity to ask questions and has indicated that she understands the information given to her. I confirm that the individual has given consent for her baby freely.

Name of Witness (print)

Signature of Witness

Date

Thumbprint of Participant's
Parent/Legal Guardian



I have accurately read or witnessed the accurate reading of the consent form to the potential participant's parent/legal guardian, and the individual has had the opportunity to ask questions and has indicated that she understands the information given to her. I confirm that the individual has given consent freely for her baby.

Name of Study Personnel (print)

Signature of Study Personnel

Date

A copy of this Informed Consent Form has been provided to the participant's parent(s) or legal guardian(s): _____ (initialed by Study Personnel).